ARC 7192B

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 124.301 and 147.76, the Board of Pharmacy hereby amends Chapter 13, "Sterile Compounding Practices," Iowa Administrative Code.

The amendments clarify the purpose and scope of the rules contained within Chapter 13 and add, delete, and modify definitions of terms used throughout the Chapter. Item 3 amends rule 13.11(155A) to specifically address defined conditions and examples of low-risk preparations and adds new subrule 13.11(3) relating to a new subset of low-risk preparations that are further identified as low-risk preparations with 12-hour or less beyond-use date. The new subrule identifies the conditions and criteria that classify a preparation within this category including the required equipment, area, personnel, and environmental processes. Standards for solid-frozen state are amended in subrules 13.11(1), 13.12(1), and 13.13(1) to comply with current industry standard temperatures for this state and conditions defining high-risk preparations are amended for clarity.

Rule 13.14(155A) is amended in Item 7 to clarify the provisions relating to immediate-use preparations, including the identification of circumstances that would qualify a preparation under this category and the detailing of processes relating to the compounding of immediate-use preparations. Requirements regarding the use of single-dose and multiple-dose vials are clarified in rule 13.15(155A).

The preferred placement of a biological safety cabinet or a compounding aseptic isolator containment and control device to be used in the sterile preparation of hazardous drugs is clarified in Item 9, and terms relating to sterilization methods are corrected and further clarified in Item 10.

Amendments adopted in Item 11 are intended to clarify the purpose for media-fill testing by personnel and provide guidance for the development of appropriate testing procedures. Redundant terms are deleted in Item 12, and Item 13 amends the requirements for periodic microbial air sampling to require semiannual sampling regardless of the level of sterile compounding engaged in at the compounding site.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the July 2, 2008, Iowa Administrative Bulletin as **ARC 6874B**. The Board received one written comment regarding the proposed amendments, suggesting that the time periods in Item 7, numbered paragraphs "4" and "5" in rule 657—13.14(155A), be amended to be consistent with industry standards and with the defined beyond-use date. The adopted amendments differ from those published under Notice. Numbered paragraphs "4" and "5" have been amended to require administration of an immediate-use preparation within one hour after compounding of the preparation is completed, which is consistent with the beyond-use date. Paragraphs "4" and "5" now read as follows:

"4. Administration begins not later than one hour after compounding of the preparation is completed."

"5. If administration has not begun within one hour after compounding of the preparation is completed, the preparation is promptly and safely discarded."

The amendments were approved during the July 29, 2008, meeting of the Board of Pharmacy.

These amendments will become effective on October 29, 2008.

These amendments are intended to implement Iowa Code sections 124.301, 126.10, 155A.2, 155A.4, 155A.13, 155A.13A, and 155A.28.

EDITOR'S NOTE: Pursuant to recommendation of the Administrative Rules Review Committee published in the Iowa Administrative Bulletin, September 10, 1986, the text of these amendments [amendments to Ch 13] is being omitted. With the exception of the changes noted above, these amendments are identical to those published under Notice as **ARC 6874B**, IAB 7/2/08.

[Filed 9/5/08, effective 10/29/08]

[Published 9/24/08]

[For replacement pages for IAC, see IAC Supplement 9/24/08.]